



27-FEB-1998-0471

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McNEIL CONSUMER
FORT WASHIF

Individual Safety Report



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A. Patient information

1. Patient identifier 017-16468216 In confidence	2. Age at time of event: or 12 mo Date of birth:	3. Sex () female (X) male	4. Weight lbs or 10 kgs
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B. Adverse event or product problem

1. X Adverse event and/or Product problem (e.g., defects/malfunctions)	
2. Outcomes attributed to adverse event (check all that apply)	() disability () death (mo/day/yr) () life-threatening (X) hospitalization - initial or prolonged () congenital anomaly () required intervention to prevent permanent impairment/damage (X) other: recovered

3. Date of event (mo/day/yr) 4/24/93	4. Date of this report (mo/day/yr) 02/11/98
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5. Describe event or problem

Case report requested from [redacted] in preparation for the FDA Nonprescription Drugs Advisory Committee Meeting on Dosing/Labeling of Pediatric Analgesics/Antipyretics held 9/18/97. Report indicates a 12 month old male was given 5 ml (500 mg) of acetaminophen drops every 3-4 hours as needed. Patient received 9 teaspoonfuls (45 ml or 4.5 gm) over 36 hours (OVERDOSE). According to report, family had misunderstood the discharge instructions. Patient presented to emergency room asymptomatic, however, LIVER FUNCTION TEST ABNORMAL. Patient's PT=15.7 and protein was found in urine (ALBUMINURIA). Therapy was initiated with n-acetylcysteine (NAC). Patient's LFT's continued to increase and PT rose to 18 (PROTHROMBIN INCREASED). Patient transferred to 2nd hospital. LFT's peaked two days following admission. Bilirubin within normal limits throughout hospitalization. Patient received entire course of NAC and was discharged home in good condition.

6. Relevant tests/laboratory data, including dates

In ER: AST=700, LDH=799, Alk Phos=214, PT=15.7; protein found in urine; acetaminophen level=25 mcg/ml; PT rose to 18; Two days following admission: AST=13,074, ALT=11,790; (See Sect 87)

7. Other relevant history, including preexisting medical conditions (e.g., allergies, race, pregnancy, smoking and alcohol use, hepatic/renal dysfunction, etc.)

unknown

Sect 86 con't: bilirubin within normal limits throughout hospitalization; last recorded AST=390 & ALT=3867

C. Suspect medication(s)

1. Name (give labeled strength & mfr/labeler, if known)		3. Therapy dates (if unknown, give duration) from/to (or best estimate)
#1	Infants' TYLENOL Drops	#1 over 36 hours; 9 doses
#2		#2
2. Dose, frequency & route used		5. Event abated after use stopped or dose reduced
#1	500 mg, q3-4h prn, po	#1 (X) Yes () No () N
#2		#2 () Yes () No () N
4. Diagnosis for use (indication)		8. Event reappeared after reintroduction
#1	unknown	#1 () Yes () No (X) N
#2		#2 () Yes () No () N
6. Lot # (if known)	7. Exp. date (if known)	10. Concomitant medical products and therapy dates (exclude treatment of event)
#1 Unknown	#1 Unknown	unknown
#2	#2	
9. NDC # - for product problems only (if known)		

G. All manufacturers

1. Contact office - name/address (& mfring site for devices)	2. Phone number
McNeil Consumer Products Company Medical Affairs 7050 Camp Hill Road Ft. Washington, PA 19034	215-233-7820
4. Date received by manufacturer (mo/day/yr) 02/03/98	3. Report source (check all that apply)
6. If IND, protocol #	() foreign () study () literature () consumer (X) health professional () user facility () company representative () distributor () other:
7. Type of report (check all that apply)	
() 5-day (X) 15-day () 10-day () periodic (X) initial () follow-up #	
8. Mfr. report number	8. Adverse event term(s)
0931690A	OVERDOSE LIVER FUNC ABNO PROTHROMBIN INC ALBUMINURIA

E. Initial reporter

1. Name, address & phone #			
[redacted]			
[redacted]			
[redacted]			
[redacted]			
2. Health professional?	3. Occupation	4. Initial reporter also sent report to FDA	
(X) Yes () No	Nurse	() Yes () No (X) Unk	



Facsimile Form 3500A

Submission of a report does not constitute an admission that medical personnel, user facility, distributor, manufacturer or product caused or contributed to the event.